

## **DETAILED ACTION**

### ***Status of objections and rejections***

1. Applicant's response and amendment filed 3/6/09 is entered.
2. Claims 37-51 are pending. Claim 51 is newly added claim. Claims 1-36 are canceled. Newly added claim 51 falls within the scope of the elected invention. Accordingly, claims 37-50, and newly added claim 51 are examined on merits in the present Office action.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Objection to claims 43 is withdrawn in light of claim amendment filed in the paper of 03/06/09.
5. Rejection of claims 37-50 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is withdrawn in light of claim amendment and persuasive arguments filed in the paper of 03/06/09.

### ***Election/restriction***

6. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

7. Claim 48 remains and newly added claim 51 is objected to because of the following informalities:

Claim 48 remains objected for not reciting the full-form of "ERECTA".

Applicant's response filed in the paper of 3/6/09 recites "the full-form of the" in lines 3-4 of claim 48. It appears Applicant has misinterpreted the objection. Applicant is requested to recite the full-form of the recitation "ERECTA". What is the full-form of the term "ERECTA". What does "ERECTA" abbreviation stand for?

Newly added claim 51 is objected for not reciting the full-form of "ERECTA".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. Claim 48 remains and newly added claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed 8/29/08.

Applicant traverses the rejection in the paper filed 3/6/09.

Applicant argues that ERECTA proteins were known in the prior art at the time of filing. Applicant cites Exhibit B to argue that about 200 Leucine-Rich-Repeat Receptor like kinases were easily recognizable by simple sequence analysis (response, paragraph bridging pages 8 and 9). Applicant further argues that same ERECTA protein may be involved in a diversity of function, and this diversity of function may be

Art Unit: 1638

due to the result of the region of the plant genome into which ERECTA is introduced, the copy number of the ERECTA which is expressed, and the degree to which the plant's endogenous ERECTA is deficient or sub optimal. Applicant further argues that the instant specification reveals that ERECTA regulates stomatal density and hence is involved in a pathway associated with stomatal patterning which is different from elongation of cells in the reproductive stems (response, paragraph bridging pages 9 and 10).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

It is important to note that the breadth of the term "ERECTA" encompasses any "ERECTA" protein isolated from any source that has the function of increasing transpiration efficiency upon expression in a plant. The instantly claimed genus encompasses any leucine rich receptor kinase protein that has the ability of increasing transpiration efficiency upon overexpression in a plant.

While the specification describes a nucleic acid sequence (SEQ ID NO: 1) encoding ERECTA protein of SEQ ID NO: 2 and its function of restoring the normal transpiration efficiency in a mutant plant defective in ERECTA gene (see pages 74-77, example 8), however, the specification fails to describe which ERECTA protein would exhibit such a characteristics and which ERECTA protein would not.

It is maintained that the specification does not describe structure of ERECTA genes isolated from diverse sources and genetic backgrounds. The breadth of the phrase "ERECTA genes" encompass diverse receptor protein kinases having extracellular LRRs (leucine rich repeats). The breadth of the phrase "ERECTA genes"

Art Unit: 1638

also encompass coding sequences and the associated promoter, terminator and enhancer encoding regions of the Applicant's broadly claimed genus.

It is maintained that the specification does not describe the structure for the sequences encompassed by Applicant's broadly claimed genus, and thus their function of enhancing transpiration rate in a plant is unknown.

It is further maintained that there is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (enhanced transpiration rate) of SEQ ID NO: 2.

Applicant is reminded that the state of the art (Shpak et al. Development, 131:1491-1501, 2004) suggests that ERECTA genes are receptor protein kinases involved in diverse cellular processes, such as, plant morphogenesis, architecture, including plant height (see abstract). Thus, Applicant's broadly claimed genus encompasses structures whose function is unrelated to the instantly claimed SEQ ID NO: 2.

Applicant is not on the point by suggesting that same ERECTA protein may exhibit different functions due to the differences in the region of the genome where transgenic ERECTA nucleic acid is integrated. Applicant has provided no basis to support this assumption.

The only species described in the specification is SEQ ID NO: 1, which encodes SEQ ID NO: 2.

Structures encompassed by the breadth of "ERECTA genes" are not described and thus their function of enhancing transpiration in a plant is unknown.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Also see *in re Curtis* (69 USPQ2d 1274 (Fed. Cir.2004)), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not predict the operability of other species other than the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the art, reading the initial disclosure, would “instantly recall” additional species of the genus already “stored” in the minds, but if other members of the genus would not “naturally occur” to a person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

For at least these reasons and the reasons of record stated in the previous Office Action, the requirement for written description has not been met. Accordingly, the rejection is maintained.

***Claim Rejections - 35 USC § 102 & 103***

9. Claims 37-50 remain, and newly added claim 51 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mitsukawa et al. (Japanese Patent Publication No. JP 09056382 A, Published March 4, 1997, translation enclosed) and evidenced by Masle et al. (Nature, 436:866-870, 2005) for the reasons of record stated in the Office action mailed 8/29/08.

Applicant traverses the rejection in the paper filed 3/6/09.

Applicant argues that Office has failed to cite any evidence that expression of Mitsukawa et al. protein (accession no. AAW13408) in a transgenic plant would necessarily result in enhanced transpiration efficiency. Applicant further alleges that Office has not provided sufficient evidence to support inherency argument (response, page 11, lines 1-20). Applicant further argues that Mitsukawa et al. do not disclose the step of selecting a plant with enhanced transcriptional efficiency as required by claims. Applicant further argues that Mitsukawa et al. disclose a different step of identifying a plant with enhanced stem length. Applicant further argues that there is no correlation between stem length and transpirational efficiency in plants with a given ERECTA. Applicant cites exhibits F and G to support these arguments (response, 4<sup>th</sup> paragraph of page 12 through 3<sup>rd</sup> paragraph of page 13). Applicant further alleges that the Office does not segregate the different phenotypes at issues here and simply blurs them in a

Art Unit: 1638

genetic phenotype and thereby ignoring Applicant's claimed invention. Applicant continues to argue that the Office has not identified any evidence which teaches that ERECTA is associated with transcriptional efficiency (response, paragraph bridging pages 13 and 14).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

It is noted that Applicant is not on the point by alleging that Office has not shown evidence for the inherent phenotype (increased transpiration efficiency).

Applicant's attention is drawn to Masle et al. at page 436, abstract, figure 1; page 867, figure 2; page 436, figures 3-4), wherein Masle et al. clearly disclose an ERECTA gene encoding a protein having 100% sequence identity to Mitsukawa et al. protein (accession no. AAW13408), and wherein expression of said gene in a transgenic plant results in enhanced transpiration efficiency. Applicant is reminded that Masle et al. disclosure provides a direct evidence for the inherency characteristics (enhanced transpiration efficiency) of Mitsukawa et al. protein.

It is unclear why Applicant is arguing that Mitsukawa et al. disclose that overexpression of their protein (accession no. AAW13408) results in increase in stem length in transgenic plant, and there is no correlation between increase in stem-length and increase in transpiration efficiency. Office has never suggested that increase in stem length would have resulted in enhancement of transpiration efficiency in the transgenic plant expressing ERECTA protein.

It is important to note that increase in stem length is another characteristics besides increase in transpiration efficiency that are inherently associated with the same

Art Unit: 1638

protein (SEQ ID NO: 2) because of its sequence identity to accession no AAW13408 (Mitsukawa et al. protein). The issue is not whether Mitsukawa et al. shows increase in stem length in transgenic plant overexpressing their ERECTA protein. Rather the issue is whether Office has provided a sufficient evidence in support of the inherency characteristics (increased transpiration efficiency). As discussed above, Masle et al. provides a sufficient evidence to support inherency characteristics of enhancement of transpiration efficiency.

It is therefore, maintained that Mitsukawa et al. disclose a method of producing a transgenic plant comprising transforming plant (*Arabidopsis*) cells with a plant transformation vector comprising a DNA construct having a gene which comprises a promoter (CaMV 35S) operably linked to a nucleotide sequence encoding the protein of accession No. AAW13408, which has 100% sequence identity to instant SEQ ID NO: 2. The reference further discloses expression of said nucleic acid sequence in the transformed cells, selection of transformed cells expressing the transgenic protein, and regenerating the transformed plant expressing the protein encoded by said nucleotide sequence. The reference also discloses obtaining transgenic seeds from the transformed plant. See in particular, claims 1-6; paragraphs 0001-0055. The reference discloses all the active method steps of instantly claimed invention.

See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and



Art Unit: 1638

thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently “rich in glucosinolates”).

Also see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

It is further maintained that instantly claimed invention encompasses a method step comprising selecting for a transgenic plant with enhanced transpiration efficiency phenotype compared to an untransformed plant. Neither the specification nor the prior art suggests that transgenic plant population expressing a polynucleotide encoding instant SEQ ID NO: 2 results in a significant proportion of transgenic plants which do not exhibit an increased transpiration efficiency phenotype. It would have been obvious to one of ordinary skill in the art to select for transgenic plant with increased transpiration efficiency (inherently associated property of polynucleotide sequence disclosed in the reference) because selection of a transgenic plant with a phenotype would have been the ultimate useful goal without any surprising or unexpected results.

It is further maintained that it would have been obvious and within the scope of an ordinary skill in the art to have been motivated to practice the method of making transgenic plant of Mitsukawa et al., in an economically important food crop, such as, rice or corn in arriving at the instantly claimed invention with a reasonable of expectation of success.

It would have been obvious and within the scope of an ordinary skill in the art to transfer the transgene of Mitsukawa et al. into untransformed plants by cross

Art Unit: 1638

hybridization of a wild-type plant with their transgenic plant. One of ordinary skill in the art would have been motivated to do so for the purpose of avoiding time-consuming and expensive method of transforming plant cells and obtaining transgenic plants thereof.

It must be noted that although Mitsukawa et al. do not explicitly disclose transgenic plants of rice, sorghum, wheat or maize, however, it would have been obvious to practice the method of Mitsukawa et al. in a economically food crop including rice, sorghum, wheat or maize with a reasonable expectation of success.

It is further maintained that Mitsukawa et al. disclose a transgenic plant and a method of producing said transgenic plant comprising introducing and expressing a nucleotide sequence encoding the protein of accession No. AAW13408, which has 100% sequence identity to instant SEQ ID NO: 2.

It is further maintained that neither the specification nor the prior art suggests that transgenic plant population expressing a polynucleotide encoding instant SEQ ID NO: 2 results in a significant proportion of transgenic plants which do not exhibit an increased transpiration efficiency phenotype. It is therefore, maintained that would have been obvious to one of ordinary skill in the art to select for transgenic plant with increased transpiration efficiency because selection of a transgenic plant with a phenotype would have been the ultimate useful goal without any surprising or unexpected results.

Accordingly claims 37-51 remain and newly added claim 51 is rejected.

### ***Conclusions***

10. Claims 37-50 remain and newly added claim 51 is rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/

Primary Examiner, Art Unit 1638